

# PUBLIC HEALTH DEPARTMENT[641]

## Notice of Intended Action

**Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)"b."**

**Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.**

Pursuant to the authority of Iowa Code sections 135.11 and 135.131, the Department of Public Health hereby gives Notice of Intended Action to amend Chapter 3, "Early Hearing Detection and Intervention," Iowa Administrative Code.

This chapter contains rules for the universal hearing screening of all newborns and infants in Iowa and the transfer of data to the Department to enhance the capacity of agencies and practitioners to provide services to children and their families. The goal of universal hearing screening of all newborns and infants in Iowa is early detection of hearing loss to allow children and their families the opportunity to obtain early intervention services. This chapter also includes rules to establish procedures for distribution of funds to support the purchase of hearing aids and audiologic services for children.

These proposed amendments eliminate unnecessary dates, clarify language regarding reporting the child's primary care provider to the Department and clarify the roles and responsibilities of the hospital and audiologist or health care provider for reporting hearing screening or diagnostic assessment results for children under the age of three to the Department. The changes facilitate timely follow-up and avoid unnecessary contact with parents and providers, as well as help the Iowa Early Hearing Detection and Intervention (EHDI) program to monitor the quality of EHDI services and provide recommendations for improving care. These changes are supported by the Early Detection and Intervention Advisory Committee.

Any interested person may make written comments or suggestions on the proposed amendments on or before August 4, 2009. Such written comments should be directed to Tammy O'Hollearn, Iowa Department of Public Health, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319-0075. E-mail may be sent to [tohollea@idph.state.ia.us](mailto:tohollea@idph.state.ia.us).

A public hearing will be held by conference call on August 4, 2009, from 9 to 10 a.m. Individuals may participate by calling 1-866-685-1580 and entering the following pass code: 0009990487 followed by the # key.

These amendments are intended to implement Iowa Code section 135.131 as amended by 2009 Iowa Acts, House File 314, division II, and 2009 Iowa Acts, House File 811, division IV, section 60(2)"c."

The following amendments are proposed.

ITEM 1. Strike "80GA,ch102" wherever it appears in the parenthetical implementation statutes of **641—Chapter 3** and insert "135" in lieu thereof.

ITEM 2. Adopt the following **new** heading before rule **641—3.1(135)**:

### EARLY HEARING DETECTION AND INTERVENTION [EHDI] PROGRAM

ITEM 3. Adopt the following **new** definitions in rule **641—3.1(135)**:

*"Applicant"* means a child for whom assistance under this program is being requested.

*"Contractor"* means the entity selected by the department to act as third-party administrator for claims payment related to hearing aids and audiologic services for children.

*"Early hearing detection and intervention advisory committee"* or *"EHDI advisory committee"* means the committee appointed by the department to advise the director of the department regarding issues related to hearing health care for children and to make recommendations about the design and implementation of the early hearing detection and intervention program.

*“Protocol”* means a document which guides decision making and provides the criteria to be used regarding screening, diagnosis, management, and treatment of children related to hearing health care. Early hearing detection and intervention protocols not otherwise specified in this chapter are available on the department’s Web site at <http://www.idph.state.ia.us/iaehdi/professionals.asp>.

*“Provider”* means a licensed audiologist, otolaryngologist or hearing aid dispenser who agrees to provide hearing aids or audiologic services to eligible patients.

*“Resident”* means an individual who is a legal resident of the state of Iowa.

ITEM 4. Amend rule 641—3.2(135) as follows:

**641—3.2(135) Purpose.** The overall purpose of this chapter is to establish administrative rules in accordance with ~~2003 Iowa Acts, chapter 102~~ Iowa Code section 135.131 as amended by 2009 Iowa Acts, House File 314, division II, relative to the following:

1. Universal hearing screening of all newborns and infants in Iowa.
2. Facilitating the transfer of data to the department to enhance the capacity of agencies and practitioners to provide services to children and their families.
3. Establishing the procedure for distribution of funds to support the purchase of hearing aids and audiologic services for children in accordance with 2009 Iowa Acts, House File 811, section 60(2) “c.”

ITEM 5. Renumber rules **641—3.4(135)** to **641—3.13(135)** as **641—3.5(135)** to **641—3.14(135)**.

ITEM 6. Adopt the following new rule 641—3.4(135):

**641—3.4(135) Program components.**

**3.4(1)** The early hearing detection and intervention (EHDI) coordinator assigned within the department provides administrative oversight to the early hearing detection and intervention program within Iowa.

**3.4(2)** The EHDI advisory committee represents the interests of the people of Iowa and assists in the development of programming that ensures the availability and access to quality hearing health care for Iowa children.

*a.* Committee membership includes representation from different facets of the health care community including the Iowa Hospital Association, private practice audiologists, pediatricians, family practice physicians and otolaryngologists.

*b.* The committee also includes representation from the deaf community, parents of children with hearing loss, advocates, Early ACCESS (IDEA, Part C), area education agencies, and other stakeholders that are affected by or involved with newborn hearing screening and follow-up.

**3.4(3)** The early hearing detection and intervention program has an association with the Iowa Title V maternal and child health programs to promote comprehensive services for infants and children with special health care needs.

ITEM 7. Amend renumbered rule 641—3.5(135), introductory paragraph, as follows:

**641—3.5(135) Screening the hearing of all newborns.** ~~Beginning January 1, 2004, all~~ All newborns and infants born in Iowa, except those born with a condition that is incompatible with life, shall be screened for hearing loss. The person required to perform the screening shall use at least one of the following procedures:

ITEM 8. Amend renumbered rule 641—3.6(135), introductory paragraph, as follows:

**641—3.6(135) Procedures required of birthing hospitals.** ~~Beginning January 1, 2004, each~~ Each birthing hospital in Iowa shall follow these procedures:

ITEM 9. Adopt the following new subrules 3.6(7) and 3.6(8):

**3.6(7)** The birthing hospital shall report the results of the hearing screening to the primary care provider of the newborn or infant upon the newborn’s or infant’s discharge from the birthing hospital. If

the newborn or infant was not tested prior to discharge, the hospital shall report the status of the hearing screening to the primary care provider of the newborn or infant.

**3.6(8)** The birthing hospital shall follow the hearing screening protocols prescribed by the department.

ITEM 10. Amend renumbered rule 641—3.7(135), introductory paragraph, as follows:

**641—3.7(135) Procedures required of birth centers.** ~~Beginning January 1, 2004, each~~ Each birth center in Iowa shall follow these procedures:

ITEM 11. Adopt the following **new** subrule 3.7(6):

**3.7(6)** The person who completes the screening shall follow the hearing screening protocols prescribed by the department.

ITEM 12. Amend renumbered subrule 3.8(1) as follows:

**3.8(1)** ~~Beginning January 1, 2004, a~~ A physician or other health care professional who undertakes primary pediatric care of a newborn delivered in a location other than a birthing hospital or birth center shall refer the newborn to an audiologist, physician, or hospital for completion of the newborn hearing screening within three months of the newborn's birth. The health care professional who undertakes primary pediatric care of the newborn shall arrange an appointment for the newborn hearing screening and report to the parent the appointment time, date, and location.

ITEM 13. Adopt the following **new** subrule 3.8(4):

**3.8(4)** The person who completes the newborn hearing screening shall follow the hearing screening protocols prescribed by the department.

ITEM 14. Amend renumbered rule 641—3.9(135) as follows:

**641—3.9(135) Reporting hearing screening results and information to the department.** ~~Beginning January 1, 2004, any~~ Any birthing hospital, birth center, physician, audiologist or other health care professional required to report information pursuant to ~~2003 Iowa Acts, chapter 102~~ Iowa Code section 135.131 as amended by 2009 Iowa Acts, House File 314, division II, shall report all of the following information to the department relating to each newborn's hearing screening within six working days of the birth of the newborn and within six working days of any hearing rescreen, utilizing the department's designated reporting system.

**3.9(1) and 3.9(2)** No change.

**3.9(3)** The name of the primary care provider for the newborn ~~at~~ upon the newborn's discharge from the birthing hospital or birth center.

**3.9(4) and 3.9(5)** No change.

**3.9(6)** Known risk indicators for hearing loss of the newborn or infant.

ITEM 15. Amend renumbered rule 641—3.10(135) as follows:

**641—3.10(135) Conducting and reporting screening results and diagnostic audiologic assessments to the department.** ~~Beginning January 1, 2004, any facility, including AEAs, Any facility, licensed audiologist or health care professional conducting newborn hearing screens, rescreens, or diagnostic audiologic assessments shall report the results of the assessments within six working days for any child under three years of age to the department utilizing the department's designated reporting system. The facility shall conduct the diagnostic hearing assessment in accordance with the Pediatric Audiologic Diagnostic Protocol contained at Appendix A. Results of a hearing screen, rescreen or diagnostic audiologic assessment shall be reported as follows:~~

**3.10(1)** Reports shall include:

a. The name and date of birth of the child.

b. The name, address, and telephone number, if available, of the mother of the child. If the mother is not the person designated as legally responsible for the child's care, the name, address, and telephone number of the parent, as defined in 641—3.1(135), shall be reported.

c. The name of the primary care provider for the child.

d. Known risk indicators for hearing loss.

~~3.10(1)~~ **3.10(2)** Results of the newborn hearing screening shall be reported as either “pass” or “refer” for each ear separately.

**3.10(3)** Results of the hearing rescreen shall be reported as either “pass” or “refer” for each ear separately.

~~3.10(2)~~ **3.10(4)** If an assessment results in a diagnosis of normal hearing for both ears, this shall be reported.

~~3.10(3)~~ **3.10(5)** Any diagnosis of hearing loss shall also be reported except for transient conductive hearing loss lasting for less than 90 days in the professional judgment of the practitioner.

~~3.10(4)~~ **3.10(6)** Reported Diagnostic audiologic assessment results shall include a statement of the severity (mild, moderate, moderately severe, severe, profound, or undetermined) and type (sensorineural, conductive, mixed, or undetermined) of hearing loss.

ITEM 16. Rescind and reserve renumbered rule **641—3.12(135)**.

ITEM 17. Reserve rules **641—3.15** and **641—3.16**.

ITEM 18. Adopt the following new heading before new rule **641—3.17(83GA,HF811)**.

HEARING AIDS AND AUDIOLOGIC SERVICES FUNDING PROGRAM

ITEM 19. Adopt the following new rules 641—3.17(83GA,HF811) to 641—3.22(83GA,HF811):

**641—3.17(83GA,HF811) Eligibility criteria.** The enrollment process to determine eligibility for services under this program includes the following requirements:

**3.17(1)** Age. Individuals are eligible from birth through 20 years of age.

**3.17(2)** Residency. Individuals must currently reside in Iowa.

**3.17(3)** The applicant must not be eligible for hearing aids or audiologic services under Title XIX or HAWK-I.

**641—3.18(83GA,HF811) Covered services.**

**3.18(1)** Funding does not cover either the surgical costs associated with a cochlear or Baha implant or the cost of the devices.

**3.18(2)** Funding does not pay for services denied by insurance because the applicant received services outside the provider network.

**3.18(3)** The following hearing aids and audiologic services may be provided through the hearing aids and audiologic services funding program:

1. Repair/modification of hearing aid
2. Hearing aid, monaural, behind the ear
3. Hearing aid dispensing fee, monaural
4. Hearing aid, binaural, in the ear
5. Hearing aid, binaural, behind the ear
6. Hearing aid dispensing fee, binaural
7. Hearing aid, bicros, glasses
8. Ear mold/insert, not disposable, any type
9. Battery for use in hearing aid
10. Hearing aid supplies, accessories
11. Assistive listening device, not otherwise specified
12. Assistive listening device, dispensing
13. Service handling charge
14. Service charge, ear mold
15. Annual charge, ear mold
16. Pure tone audiometry, air only
17. Pure tone audiometry, air and speech audiometry threshold

18. Speech audiometry threshold
  19. Speech audiometry threshold with speech
  20. Comprehensive audiometry threshold evaluation
  21. Tympanometry (impedance testing)
  22. Conditioning play audiometry
  23. Auditory-evoked potentials for evoked response audiometry, comprehensive
  24. Auditory-evoked potentials for evoked response audiometry, limited
  25. Visual reinforcement audiometry
  26. Evoked otoacoustic emissions, limited
  27. Hearing aid examination and selection, monaural
  28. Hearing aid examination and selection, binaural
  29. Hearing aid check, monaural
  30. Hearing aid check, binaural
  31. Electroacoustic evaluation for hearing aid, monaural
  32. Electroacoustic evaluation for hearing aid, binaural
  33. Office/outpatient visit related to audiology services
  34. Consultations related to audiology services
- 3.18(4)** The department may elect to cover additional services not otherwise restricted in these rules.

**641—3.19(83GA, HF811) Application procedures.**

**3.19(1)** A child, or the parent or guardian of a child, desiring hearing aids or audiology services may apply to the contractor.

**3.19(2)** The following information shall be provided to the contractor by the applicant to be considered for eligibility under this program:

- a. Patient's first name, middle initial and last name.
- b. Patient's date of birth.
- c. Patient's address, including city, state and ZIP code.
- d. Parent/guardian's first name, middle initial and last name.
- e. Parent/guardian's telephone number.
- f. Parent/guardian's E-mail address.
- g. Parent/guardian's or child's medical insurance plan name.
- h. Hearing aid/audiology service provider name and telephone number.
- i. Whether the request is for hearing aids or audiology services or both.
- j. Estimated service costs.

**3.19(3)** Applicants will be enrolled in the program on a first-come, first-served basis upon the date the application is received by the contractor.

**3.19(4)** The contractor will provide written notification to the applicant regarding determination of eligibility or noneligibility and the applicant's right to appeal a denial. For those applicants deemed eligible, an enrollee number will be assigned by the contractor.

**3.19(5)** An applicant must submit a renewal application form on an annual basis, accompanied by all information requested by the department.

**641—3.20(83GA, HF811) Hearing aids and audiology services funding wait list.**

**3.20(1)** If an applicant is eligible for hearing aid and audiology services funding and sufficient funds are available to provide services to the applicant, the contractor shall enroll the applicant upon approval by the department. If the applicant is eligible for hearing aid and audiology services funding and sufficient funds are not available to provide services to the applicant, the contractor upon approval by the department shall place the applicant's name on the hearing aid and audiology services funding wait list in the order provided for in this rule.

**3.20(2)** The contractor, upon approval by the department, shall place names on the wait list in the following order:

- a. Applicants under the age of three diagnosed with a hearing loss who are in need of hearing aids.

- b. Applicants in need of hearing aids or audiologic services.
- c. All other applicants, who shall be placed on the wait list in chronological order based upon the date of receipt of a completed application by the contractor upon approval by the department.

**641—3.21(83GA, HF811) Reimbursement of providers.**

**3.21(1)** To receive reimbursement for hearing aids and audiologic services, the provider must complete a provider information sheet and I-9 form provided by the department.

**3.21(2)** The provider must be a Title XIX provider.

**3.21(3)** Reimbursement of hearing aids and audiologic services will be paid directly to the provider based on Title XIX reimbursement rates.

a. Bills will be adjusted accordingly by the department prior to payment.

b. Reimbursement for hearing aids or supplemental hearing devices includes the costs of shipping and handling.

**3.21(4)** Hearing aids and audiologic services funding shall be the payor of last resort.

**3.21(5)** Payment through this funding source is considered payment in full for covered services. If a third party liability (TPL) payment equals or exceeds the Title XIX allowance, no further reimbursement is provided.

**3.21(6)** The provider shall submit bills after an enrollee number is assigned to the applicant and the audiologic service is provided or hearing aid is fitted.

**3.21(7)** The provider shall submit the following documents:

a. Health Care Financing Administration Form HCFA 1500. Forms will be furnished by the providers and will include the applicant's enrollee number in the upper right-hand corner of the form.

b. Manufacturer's invoice for hearing devices as prescribed by the department.

c. Applicant's explanation of benefits or documentation of a telephone contact made by the provider to the patient's private insurance company including: date of contact, name of insurance representative, name of insurance company, applicant's policy number and coverage limitations for hearing evaluations and devices.

**641—3.22(83GA, HF811) Appeals.** The department shall cause an applicant to be notified of the department's decision to approve or deny an application or to place an applicant on the child hearing aids and audiologic services wait list. In the event an applicant is dissatisfied with the department's decision, the applicant may submit a formal appeal in writing to the EHDI advisory committee. Such request shall be delivered in person or shall be mailed by certified mail, return receipt requested, to EHDI Advisory Committee, Iowa Department of Public Health, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319. Upon receipt of such an appeal, the EHDI advisory committee shall review the case and issue a written determination within 15 days of receipt of the request. The decision shall refer to the applicant by initials or other nonidentifying means. The EHDI advisory committee's decision shall be final and binding. This appeal process does not constitute a contested case proceeding as defined in Iowa Code chapter 17A.

ITEM 20. Amend **641—Chapter 3**, implementation sentence, as follows:

These rules are intended to implement ~~2003 Iowa Acts, chapter 102.~~ Iowa Code section 135.131 as amended by 2009 Iowa Acts, House File 314, division II, and 2009 Iowa Acts, House File 811, division IV, section 60(2) "c."

ITEM 21. Amend **641—Chapter 3, Appendix A**, second unnumbered paragraph, as follows:

Infants should be referred for a diagnostic evaluation after receiving a "refer" result from one or both ears on a newborn hearing screening and a hearing rescreen performed at two to six weeks of age. Timely referral for diagnostic auditory brainstem response (ABR) testing may negate the need for sedation for this test in very young infants. Infants who are identified at risk for congenital or late-onset hearing loss (JCIH, ~~2000~~ 2007) should receive ~~audiologic monitoring and follow-up by age appropriate test procedures at six-month intervals until the age of five years.~~ an audiologic assessment at least once

by 24 to 30 months of age. Children with risk indicators that are highly associated with delayed-onset hearing loss, such as having received ECMO or having congenital CMV infection, should have more frequent audiologic assessments based on infant or toddler needs. All infants for whom the family has significant concerns regarding hearing or communication should be promptly referred for an audiologic and speech-language assessment.